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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,388	02/23/2004	Neil C. Leatherbury	121-02	6576

23713 7590 01/11/2007  
GREENLEE WINNER AND SULLIVAN P C  
4875 PEARL EAST CIRCLE  
SUITE 200  
BOULDER, CO 80301

EXAMINER
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REIMERS, ANNETTE R

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

NT  
Application No.

10/785,388

Applicant(s)

LEATHERBURY ET AL.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,7 and 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8 and 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's arguments regarding the restriction requirement of August 25, 2006 are persuasive. The restriction from August 25, 2006 has been vacated with the original restriction of December 23, 2005 has been reinstated. As such, claims 4, 6-7 and 9-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 5, 2006.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofstatter (US Patent Number 5,860,946).

Hofstatter discloses a bone or cartilage implant delivery device comprising a tubular outer shaft, e.g. 1, having a proximal and distal end, a longitudinal axis, and an internal bore along the longitudinal axis of the outer shaft, wherein the distal end of the outer shaft is suitable for holding an implant at 3, and an inner shaft, e.g. 2, having a distal end and a proximal end, wherein the proximal end of the inner shaft is suitable for

Art Unit: 3733

insertion into a defect, the inner shaft adapted to fit within the internal bore of the outer shaft so that the inner shaft and the outer shaft are slidably engaged, wherein one or more of the shafts comprise means to provide friction-retarded movement of the inner shaft through the outer shaft, also comprising an implant disposed within the distal end of the outer shaft, also comprising at least one slot in the distal end of the outer shaft for visualizing the implant, wherein the proximal and distal ends of the inner and outer shafts have smooth, rounded surfaces (see various embodiment of figures 1-6 and abstract).

It is noted that the preamble of claim 1 recites "A bone or cartilage implant delivery device" which amounts to an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Furthermore, with regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Hofstatter, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

Claims 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart et al. (US Patent Number 5,782,835), cited by applicant.

Hart et al. disclose a method for delivering a bone or cartilage implant into a defect in a tissue having an unmeasured depth using an implant delivery device comprising a tubular outer shaft having a proximal and distal end, a longitudinal axis, and an internal bore along the longitudinal axis of said outer shaft, an inner shaft having a distal end and a proximal end, wherein said proximal end of the inner shaft is suitable for insertion into a defect, said inner shaft adapted to fit within said internal bore of the outer shaft so that the inner shaft and the outer shaft are slidably engaged, said method comprising the steps inserting said implant into the distal end of said outer shaft, wherein when said implant is disposed in said outer shaft, the proximal end of the inner shaft protrudes from the proximal end of the outer shaft and the length of said implant and equals the length of the protruding section of the inner shaft, inserting the proximal end of the inner shaft into the defect until the proximal end of the inner shaft contacts the bottom of the defect, advancing the outer shaft in the proximal direction until the proximal end of the outer shaft contacts the surface of tissue surrounding the defect, causing a portion of the implant to extend beyond the distal end of the outer shaft, cutting off the portion of the implant extending beyond the distal end of the outer shaft, leaving a remaining portion disposed within the outer shaft, placing the distal end of the outer shaft over the defect and distally advancing the inner shaft to push the portion of the implant remaining after cutting into the defect, further comprising placing a cap around the distal end of the outer shaft after the

Art Unit: 3733

portion of the implant extending beyond the distal end of the outer shaft has been cut off and adding a bioactive fluid to the distal end of said outer shaft (see figures 6-8D). Hart et al. also disclose a kit including an implant and a knife (see column 3, lines 5-13).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hart et al. (US Patent Number 5,782,835), cited by applicant, in view of Smith et al. (US Patent Number 5,697,932), cited by applicant.

Hart et al. disclose the claimed invention except the kit containing a plurality of bone delivery devices. Smith et al. disclose a kit and the use of different sized instruments to accommodate surgical needs. It would have been obvious to one skilled in the art at the time the invention was made to construct the kit of Hart et al with a plurality of bone delivery devices, in view of Smith, to accommodate surgical needs.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-3, 5, 8 and 24-29 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER